IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNIVERSITY OF MASSACHUSETTS and CARMEL LABORATORIES LLC, Plaintiffs, v. L'ORÉAL USA, INC., Defendant.	)	C.A. No. 17-868-CFC-SRF **PUBLIC VERSION**

MOTION NO. 1: L'ORÉAL USA'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF INDEFINITENESS OF THE DERMAL CELL ADENOSINE CONCENTRATION CLAIM LIMITATION

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TABLE OF EXHIBITS[1]

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1	U.S. Patent No. 6,423,327, issued to Dobson, Jr. et al. on July 23, 2002
2	U.S. Patent No. 6,645,513, issued to Dobson, Jr. et al. on November 11, 2003
5	Declaration of Gerald B. Kasting, Ph.D., containing true and correct excerpts from the Expert Report of Professor Gerald B. Kasting, Ph.D., dated June 26, 2020
7	Declaration of Gerald B. Kasting, Ph.D., containing true and correct excerpts from the Reply Expert Report of Professor Gerald B. Kasting, Ph.D., dated August 7, 2020
11	Excerpts from the Expert Report of Bozena Michniak-Kohn, Ph.D., dated June 26, 2020
12	Excerpts from the Rebuttal Expert Report of Bozena Michniak-Kohn, Ph.D. Regarding Validity, dated July 21, 2020
17	Excerpts from the deposition transcript of James Dobson, taken May 27, 2020
18	Defendant's Exhibit 1, entered during the deposition of James Dobson, taken May 27, 2020
20	Excerpts from the deposition transcript of Edward Kisak, Ph.D., taken August 12, 2020
22	Excerpts from the deposition transcript of Bozena Michniak-Kohn, Ph.D., taken August 18, 2020
32	Parties' Joint Claim Construction Brief (D.I. 97), filed March 6, 2020
33	Excerpts from the Claim Construction hearing transcript, dated April 6, 2020

[1] "Ex. __" refers to exhibits attached to the Declaration of Nicholas A. Tymoczko in Support of L'Oréal USA, Inc.'s *Daubert* and Summary Judgment Motions, filed concurrently herewith.

I. NATURE AND STAGE OF PROCEEDINGS

Plaintiffs filed this action on June 30, 2017, asserting that L'Oréal USA infringes U.S. Patent Nos. 6,423,327 ("the '327 patent") and 6,645,513 ("the '513 patent") (together, the "patents-in-suit"). (D.I. 1.)[2] Both fact discovery and expert discovery have closed. A jury trial is scheduled for February 8, 2021.

II. SUMMARY OF ARGUMENT

1. In their sole respective independent claims, each of the patents-in-suit recites a method for improving the condition of unbroken mammal skin by topically applying a composition containing the chemical compound adenosine,[3] "***wherein the adenosine concentration applied to the dermal cells is 10^{-4} M to 10^{-7} M [or "10^{-3} M to 10^{-7} M," i.e., a specific concentration range]***." In *Markman* proceedings, Plaintiffs proposed, and the Court accepted, that these numerical concentration limitations refer to the concentration of adenosine that "reaches" the "dermal cells." (*See, e.g.*, Ex. 33 at 10:25-11:3, 57:17-18; Ex. 32 at 1, 6; D.I. 114.) Accordingly, when topically applying a composition to unbroken mammal skin,

[2] Unless otherwise noted, all emphases have been added and all internal citations, modifications, and quotations have been omitted. The patents-in-suit share a specification and citations are generally provided for the '327 patent only.

[3] This case does not involve the discovery of adenosine, which occurs naturally in the human body and was also known in the cosmetic arts since at least the early 1970s. (Ex. 5, ¶¶ 44-45.)

the question of what concentration of adenosine "reaches" those cells is critical to answering whether or not that composition falls within the scope of the claims.[4]

2. Neither the claims, the specification, nor the prosecution history identify ***any*** test by which the amount actually reaching the dermal cells is measured. And in attempting to prove infringement, Plaintiffs did not measure dermal cell concentration after applying a topical composition to unbroken skin. Instead, Plaintiffs contend that surrogate forms of testing may be used.

3. There is no dispute, however, that these surrogate tests will yield significantly different outcomes depending on the parameters used. For example, tests can be performed with different types of tissue samples from different sources using different "tracers" to measure the compound of interest. Indeed, Plaintiffs' testing has produced self-contradictory results regarding their assertions of infringement when varying just one of these parameters, *i.e.*, the tissue donor.

4. Where, as here, a patent claims a value, with no guidance within the patent regarding how to actually test for that value and different forms of testing yield conflicting results, the Federal Circuit and district courts, following the Supreme Court's *Nautilus* decision, have held such patents indefinite as a matter of law.

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[4] L'Oréal USA preserved its indefiniteness arguments throughout the claim construction process. (Ex. 32 at 20 n.3.)

5. Because the asserted claims of the patents-in-suit are invalid as indefinite, L'Oréal USA requests that the Court grant summary judgment.

III. FACTUAL BACKGROUND

The relevant facts are set forth in the Concise Statement of Facts ("SOF").

IV. LEGAL STANDARDS

A. Summary Judgment

Summary judgment is warranted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Questions of law such as indefiniteness may be decided at summary judgment. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015); *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1356 (Fed. Cir. 2005), *abrogated on other grounds by Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014).

B. Indefiniteness

An essential tenet of patent law is that a patent claim must provide clear public notice of its metes and bounds. *See, e.g., Dow Chem. Co. v. Nova Chem. Corp. (Canada)*, 803 F.3d 620, 630 (Fed. Cir. 2015). Accordingly, in 2014, the Supreme Court ruled that a "patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the

invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). The interpretation of the patent specification and prosecution history is a matter of law for the Court, as is the ultimate question of indefiniteness. *See Teva Pharms.*, 789 F.3d at 1339, 1341; *HZNP Med. LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 688 (Fed. Cir. 2019).

Where there are "multiple methods" of evaluating a claim term that "lead[] to different results" and there is a lack of "guidance in the patent or the prosecution history as to which method should be used," the claim term is indefinite. *See, e.g.*, *Dow Chem.*, 803 F.3d at 634; *Butamax™ Advanced Biofuels LLC v. Gevo, Inc.*, 117 F. Supp. 3d 632, 641-42 (D. Del. 2015) (granting summary judgment where "multiple legitimate methods exist . . . and such methods of measurement can yield different results").

V. ARGUMENT

A. The Intrinsic Record Does Not Provide Guidance Regarding How to Determine the Results Required by the Claims

At Plaintiffs' request, the Court construed the claims as requiring a concentration of adenosine that reaches or penetrates to the dermal cells following topical application to the skin. (*See* SOF, ¶ 4.) Having obtained this construction, the question then becomes how to determine whether or not that limitation is met.

The patent claims, specification, and prosecution history, however, neither disclose how to ascertain that value nor contain any testing for that value. (SOF,

¶ 5.) Instead, the only methodologies discussed in the patent involve "*in vitro* cell culture" experiments (*i.e.*, Petri dish experiments that do not involve topical applications to the skin) and general descriptions of assessing skin condition improvements, including subjectively. (Ex. 1 at 5:44-6:4, 6:15-9:50.) Indeed, at deposition, Plaintiffs' Rule (30)(b)(6) designee and named inventor, Dr. James Dobson, admitted that the patent does "not discuss how to measure the concentration of adenosine that reaches the dermal layer after topical application of a composition containing adenosine." (*See* Ex. 17 at 176:5-12; *id.* at 177:4-8 (agreeing that "there's no discussion at all regarding how to measure the amount of adenosine at the dermal cell layer in the patent").[5] Plaintiffs' expert, Dr. Bozena Michniak-Kohn, likewise agreed that the '327 patent does not "mention anything about how to measure the concentration of the adenosine that reaches the dermis after topical application." (Ex. 22 at 80:14-22; *id.* at 81:18-20.)

B. The Post-Hoc Methodologies for Measuring the Claimed Values Proposed by Plaintiffs in This Case Give Varying Results, Demonstrating Indefiniteness

In attempting to prove infringement, Plaintiffs rely on "*in vitro* permeation testing" not discussed in the patents. (SOF, ¶¶ 7-8.)[6] In such tests, a composition

[5] (*See also id.* at 34:8-18, 35:9-21, 36:4-7 & Ex. 18 at 9-10.)

[6] It is undisputed that other methodologies exist to measure dermal cell concentration. (SOF, ¶¶ 6, 23.)

is not applied to "unbroken skin" as claimed, and the dermal cell concentration is thus not determined per the claims. (SOF, ¶ 9.) Instead, in this test, a membrane (such as an excised piece of skin) is mounted to an apparatus called a "diffusion cell"; a composition of interest (plus other materials that may have been added to the composition) is applied to the piece of skin for a given period of time; and a measurement is made of the extent, if any, to which the composition or compound permeated through the different layers of the skin (or into receptor fluid at the bottom of the cell). (Ex. 11, ¶ 73.)

The problem with this testing approach, as admitted by Plaintiffs' own testing expert, Dr. Edward Kisak, is that "there is no single way to do an in vitro permeation test to study the distribution of cosmetic products in the skin." (Ex. 20 at 43:15-22; *id.* at 51:17-23.) Likewise, as Plaintiffs' other expert, Dr. Michniak-Kohn, conceded, "different methods for conducting dermal penetration studies were available to a skilled artisan in 1997-1998." (Ex. 12, ¶ 177; SOF, ¶ 10.)

And, in conducting these types of tests, a scientist can make various choices that will affect the outcome, *e.g.*, different kinds of skin samples, diffusion cell types, periods of time to measure the diffusion, and materials (called "tracers") for labeling the adenosine for measurement. (SOF, ¶ 11.) For example, the piece of skin used may be from a cadaver or surgically excised tissue (and stored under different conditions, *e.g.*, fresh or frozen); it may have different thicknesses and

come from different parts of the body (*e.g.*, abdomen, back, breast, or arms); and the skin can have different qualities depending on the donor, including their gender, race, and age. (SOF, ¶¶ 11-12.) Likewise, the diffusion cell can have different designs, including configuration (*e.g.*, static or flow-through) and materials (*e.g.*, glass, Teflon, stainless steel, or plastic), and the amount of applied dose, the duration of exposure, and the type of tracer molecule may all vary. (SOF, ¶ 13.)

These factors, alone or in combination, can significantly affect the results of *in vitro* permeation tests. (SOF, ¶ 14.) For example, Dr. Dobson testified: "The operator, the type of tissue used, the conditions under which the apparatus was utilized, the temperature, the pressure exerted to the top chamber. All those are factors that could affect the results." (Ex. 17 at 348:2-349:8 (further testifying that such differences would be "statistically significant").) Similarly, it is undisputed that, for the piece of skin used, there is donor-to-donor variability, and that the age, gender, and race of the donor as well as the location from which the skin is taken will affect its permeability. (SOF, ¶ 16.) In addition, both Dr. Dobson and Dr. Michniak-Kohn acknowledged that the amount of product applied, and the duration of exposure of the skin to the composition, will affect the concentration of adenosine permeating the skin. (SOF, ¶ 17.) Nor has Dr. Michniak-Kohn disputed the opinions of Dr. Gerald Kasting, L'Oréal USA's expert, that varying these

parameters will significantly affect the results of *in vitro* permeation studies. (*See* SOF, ¶ 18.)

Plaintiffs' own infringement testing demonstrates the dangers of the variability. When Plaintiffs first ran certain of their tests for purposes of this litigation, they failed to show infringement for many of the accused products. (*See* Ex. 7 at Appendix D.) They then altered the donor, or reran the test, and claimed to obtain different results for the same product. (*See* Ex. 20 at 167:13-24, 200:15-25, 201:7-14 ("[Q.] So depending on the skin donor used, the ***same L'Oréal product*** may be found to deliver a concentration of adenosine to the dermis of ***greater than 10 to the minus 7 molar or less than 10 to the minus 7 molar***; correct? . . . THE WITNESS: That's what we observed for this product."); Ex. 7, ¶ 99, Appendix D; SOF, ¶¶ 19-20.)[7] Indeed, the results for individual replicates of a given test involving the same skin donor often varied substantially, such that some were above 10^{-7} M and others were below. (SOF, ¶ 22.) Nevertheless, Plaintiffs are accusing these products of infringement.

In sum, Plaintiffs' claim construction, as adopted by the Court, requires a certain adenosine concentration at the dermal cells when a composition is topically

[7] For example, Dr. Kisak tested the product Vichy Neovadiol Eye and Lip Contours twice using different donor skin for the two tests and reported results above and below 10^{-7} M. (Ex. 7 at Appendix D, p. 5, Entry No. 118.)

applied to unbroken mammal skin, but the patent does not disclose how to conduct that measurement. Plaintiffs have offered post-hoc techniques, the results of which can vary significantly—including with respect to whether they meet the claims or not—depending on how they are performed. The intrinsic record thus does not reasonably inform a person of ordinary skill in the art which methods to use, creating the ability seen here for Plaintiffs to pick and choose methodologies. This contravenes the principles espoused by the Supreme Court in *Nautilus*, and is the fundamental problem identified by the Federal Circuit and this Court in explaining why such patent claims are indefinite. *See, e.g.*, *Dow Chem.*, 803 F.3d at 634 ("Neither the patent claims nor the specification here discusses the four methods or provides any guidance as to which method should be used or even whether the possible universe of methods is limited to these four methods."); *see also HZNP Med.*, 940 F.3d at 698 (claims indefinite where claimed parameter could be assessed using two tests that "do not provide consistent results"); *Teva Pharm.*, 789 F.3d at 1341 (claim term "molecular weight" was indefinite where "each of these measures is calculated in a different way and would typically yield a different result for a given polymer sample"); *Butamax™ Advanced*, 117 F. Supp. at 641-42.

VI. CONCLUSION

For the reasons set forth above, L'Oréal USA respectfully requests that the Court grant summary judgment of indefiniteness of the patents-in-suit.

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CERTIFICATE OF SERVICE

I hereby certify that on September 11, 2020, a true and correct copy of the foregoing document was filed with the Clerk of Court via CM/ECF which will send notification of such filing to counsel of record and I further certify that a true and correct copy of the foregoing document was caused to be served on the following counsel of record as indicated:

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